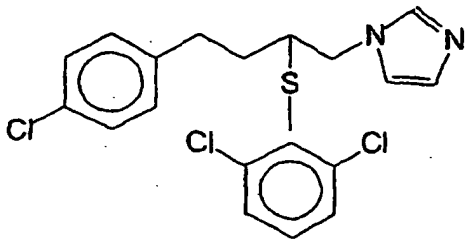
CLAIM AMENDMENTS

Claims 1 through 11 (canceled)

12. (new) High purity butoconazole nitrate salt of the Formula (I)

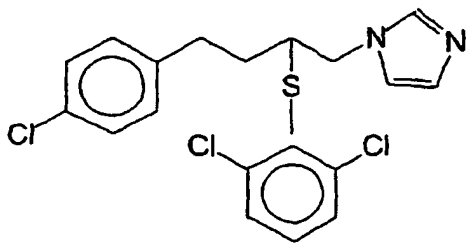


(I)

containing a maximum 0.1 wt % of chemical impurities.

13. (new) High purity butoconazole nitrate salt according to claim 12, wherein at least 95 % of the particles of the salt are below 75 μm in diameter, and wherein at least 99 % of the particles of the salt are below 250 um in diameter.

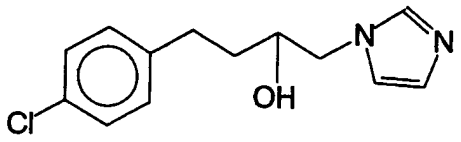
14. (new) A process for the preparation of a high purity butoconazole nitrate salt of the formula (I)



(I)

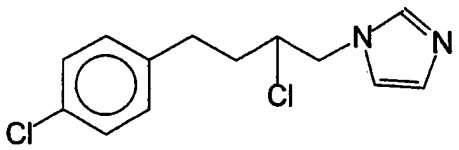
comprising the steps of:

a) reacting 1-chloro-4-chlorophenyl-2-butanol with imidazole in a mixture of a water immiscible solvent and an aqueous solution of alkali metal hydroxide or carbonate in the presence of a phase transfer catalyst to yield a compound of the Formula IV



(IV)

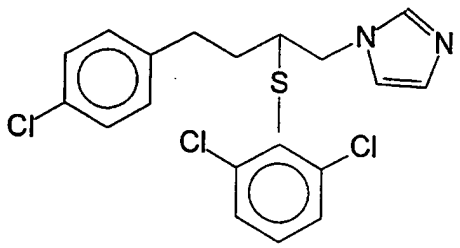
(b) reacting the compound formula of the (IV) obtained in step a), with thionyl chloride in 1,2-dichloroethane as a solvent in the presence of dimethylformamide, whereas 1-1.2 mol of thionyl chloride reagent is used based on the amount of the compound of the formula (IV) to yield a compound of the formula (V)



(V)

and

(c) reacting the compound of the formula (V) obtained in step b), with 2,6-dichlorothiophenol to obtain the compound of the Formula (VI)



(VI)

and without isolation of the compound of the Formula (VI), which remains in solution, adding nitric acid and isolating as a product the butoconazole nitrate salt of the Formula (I) having a maximum 0.1 wt % of chemical impurities.

15. (new) A process according to claim 14, wherein according to step (a) the water immiscible solvent is an aromatic hydrocarbon.

16. (new) A process according to claim 15,wherein the aromatic hydrocarbon is toluene.

17. (new) A process according to claim 14, wherein according to step (a) the alkali metal hydroxide or carbonate is respectively sodium hydroxide or sodium carbonate.

18. (new) A process according to claim 14, wherein according to step b), thionyl chloride is used in an amount of 1.1 mol per mole of the compound of the Formula (IV).

19. (new) A process for the preparation of a high purity butoconazole nitrate salt, wherein at least 95 % of the particles of the salt are below 75 μm in diameter, and whereas at least 99 % of the particles of the salt are below 250 um in diameter, which comprises the steps of:

(a) dissolving the butoconazole nitrate salt starting material in a mixture of methanol and methyl isobutyl ketone of 1-1.5 : 1 ratio (v/v) to form a solution;

(b) adding the solution formed according to step (a) to methyl isobutyl ketone cooled to a temperature between 5° and -15°C' and

(c) isolating the desired product.

20. (new) A process according to claim 19, wherein according to step (b) the cooling temperature is between -5°C and -10°c.

21. (new) A process according the claim 19, wherein according to step (a) the mixture of methyl alcohol and methyl isobutyl ketone for dissolving the butoconazole nitrate salt starting material is employed in a volume ratio of methanol/methyl isobutyl ketone of 1.25 : 1.

22. (new) An antimicrobial pharmaceutical composition comprising as active ingredient a therapeutically effective amount of the high purity butoconazole nitrate salt defined in claim 12 in admixture with a pharmaceutically acceptable inert carrier.

23. (new) The high purity butoconazole nitrate salt containing a maximum 0.1 wt % of chemical impurities, prepared by the process defined in claim 14.

24. (new) The high purity butoconazole nitrate salt, wherein at least 95 % of the particles of the salt are below 75 μm in diameter, and wherein at least 99 % of the particles of the salt are below 250 um in diameter, prepared by the process defined in claim 19.